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केन्द्रीय भेषजी
Central Pharmacy

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All India Institute of Medical Sciences, Raipur, Chhattisgarh.

(An autonomous premier institute under Ministry of Health & Family Welfare
Government of India under Pradhan Mantri Swasthya Suraksha Yojna-PMSSY)

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Superintendent/Faculty in charge Pharmacy (FIP)/ Essential Narcotic Drug Officer, All India Institute
of Medical Science Raipur, Chhattisgarh.

| Document No. | TITLE | | |
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| AIIMS/Raipur/ Policy/01 | Standard Operating Procedure (SOP) for Narcotics and Controlled drugs. | | |
| Effective date: | | | |
| Function | Name | Designation | Signature with seal |
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| Document no.: AIIMSR/Policy/NDPS | SOPs on Narcotics and Controlled drugs | |
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आरोग्यम् सुख सम्पदा

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Annexure for Abbreviations

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| PMSSY | Pradhan Mantri Swasthya Suraksha Yojna |
| AIIMS | All India Institute Of Medical Sciences |
| DTC | Drug and Therapeutic Committee |
| DMS | Deputy Medical Superintendent |
| FIP | Faculty In charge Pharmacy |
| SOP | Standard Operating Procedure |
| CEO | Chief Executive Officer |
| OIC | Office In Charge |
| OPD | Out Patient Department |
| ICUs | Intensive Care Units |
| OT | Operation Theater |
| IT | Information Technology |
| ANS | Assistant Nursing Superintendent |
| SNO | Senior Nursing Officer |
| NO | Nursing Officer |
| FIFO | First In First Out |
| FEFO | First Expiry First Out |
| T&E | Trauma & Emergency |
| NDPS | Narcotic Drugs and Psychotropic Substances |
| NCB | Narcotic Consumption Book |
| NRB | Narcotic Requisition Book |
| GRN | Goods Receipt Note |
| ADR | Adverse Drug Reaction |
| ADE | Adverse Drug Event |
| ENDs | Essential Narcotic Drugs |
| ENDOI | Essential Narcotic Drug Officer In-charge |

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Procedure for maintaining Narcotics and Controlled drugs at Central Pharmacy and Departments across the hospital.

- 1.0 Purpose-**This policy reviews the general procedures for the security and handling of Narcotic Drugs throughout the Hospital. Separate procedures address specific areas of Narcotic Drugs handling, such as the ordering, record-keeping and auditing, distribution, and annual inventory of Narcotic Drugs.
- 2.0 General:-**NDPS act 1985 governs the handling of controlled substances. All India Institute of Medical Sciences Raipur and its Pharmacy/ nursing department/user department must comply the same.

Narcotic Drugs and controlled drugs stored in a securely locked cabinet. However, pharmacies may disperse such substances throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

Narcotic and controlled drugs in securely locked cabinets with perpetual inventory. A high potential for theft or diversions are maintained in securely locked cabinets with perpetual inventory. A master list of security requirements for each drug will be maintained in NDPS the controlled substances area.

3.0 Policy

- 3.1 Strict accounting of all Narcotic & controlled drugs is necessary in order to comply with NDPS act 1985 regulations.
- 3.2 Distribution of all Narcotic & controlled substances requires a valid physician order/Department Indent.
- 3.3 Each dose of a Narcotic & controlled substance is documented according to specific procedures patient wise at user level.
- 3.4 Policy violation results in disciplinary action

4.0 Protocol

4.1 Physician Orders and Documentation

- 4.1.1 Only RMP (Registered Medical Practitioner) can order controlled substances.
- 4.1.2 Verbal orders for controlled substances must be authorized by the physician within 12 hours
- 4.1.3 Prior to administration of narcotics drugs, proper documentation must occur and same shall be ensured by ANS of respective department.
- 4.1.4 Control of medications during infusion is maintained with the use of portless tubing, patient controlled analgesia pumps, epidural infusion pumps or as preferred by prescriber.
- 4.1.4 All documentation related to administration and waste of a Narcotic drug on a patient is made on the Narcotic Consumption Book (NCB) and same shall be cross checked by ANS of respective department.

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4.1.5 The time that the drug is given and the initials of the officer /staff/prescriber who administers the drug are recorded on the NCB.

4.2 Employee Screening

3.2.1 The pharmacy will follow guidelines of the NDPS Act / sensitize the Nursing officers via training to avoid unauthorized use of controlled substances.

4.3 Employee Responsibility

4.3.1 The Staff designated by Faculty In charge Pharmacy, Hospital store – procurement, respective indenting department are responsible for NDPS drugs procurement, Storage and distribution and keep the relevant records.

4.3.2 The Assistant Nursing Superintendent (ANS)/ Senior Nursing Officers (SNO) / Nursing Officers (NO) are responsible for the administration and discard the unused portion of the injections and keep the relevant records.

4.3.3 The prescriber is responsible for the controlled use of the NDPS drugs and can pass verbal order unusual circumstances and updating of the same.

4.3.4 The **Essential Narcotic Drug Officer** is responsible for monitoring of controlled use of NDPS drugs.

4.3.5 The ANS/Unit/Area In charge Pharmacy/Nursing Officers/ Essential Narcotic Drug Officer responsible for conducting a daily visual audit of the required documentation of Narcotic and controlled Drugs.

4.4 Illicit Activities by Employees

4.4.1 It is the employees, who possess, sell, use or divert controlled substances, will subject themselves not only to Legal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment after following due inquiry into it and due approval of competent authorities.

4.4.2 In addition, the employer will assess the seriousness of the employee's violation, the position or responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate, or take other action against the employee.

5.0 Procedures

5.1 Procurement

5.1.1 On the basis of Annual consumption of Narcotic drugs the monthly/annual quota of Narcotic drugs fixed under NDPS license/approval from competent authority.

5.1.2 Procurement of Narcotic drugs done by Hospital store – procurement unit under supervision of Faculty In charge Pharmacy/ Essential Narcotic Drug Officer and after receiving by Central Pharmacy same shall be issued to respective wards against valid indent/requisition approved by competent authority AIIMS Raipur.

5.1.3 Procurement of Narcotic drugs has been done only through authorized vendors or through the governmental mechanism that exist time to time.

5.2 Storage

5.2.1 Narcotic & controlled drugs storage and inventory management done by Central Pharmacy and User Departments.

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- 5.2.2 Narcotic & Controlled drugs stored in double lock cupboards in Central Pharmacy and User Departments to prevent from theft & misuse.
- 5.2.3 Stock of Narcotic & controlled drug counted on each shift change and over given to next shift person.
- 5.3 Procedure of Narcotic Requisition and Issuing by Pharmacy**
- 5.3.1 Central Pharmacy issue Narcotic drugs only to AIIMS Raipur respective ward/ICU/OT on a written prescription/indent/requisition having prescribing doctor registration number, signature, their rubber stamp and quantity required.
- 5.3.2 No cutting and overwriting allowed in Narcotic indent book, If an error occur it should be cross by a single line and mark "ERROR" then signed by two nursing officers or doctor.
- 5.3.3 Central Pharmacy keeps the original copy of Narcotic requisition/prescription/indent and carbon copy kept in ward.
- 5.3.4 Central Pharmacy after receiving Narcotic drug requisition online and through Narcotic Requisition book issue the medicine to desired ward and maintain the issue record in the Pharmacy Narcotic Log Book.
- 5.3.5 No cutting and overwriting allowed in Pharmacy Narcotic Log Book. If an error occurs it should be cross by a single line and mark "ERROR" then signed by two pharmacists.
- 5.3.6 Pharmacy Narcotic Log Book counter checked and signed by Faculty in charge Pharmacy/ Essential Narcotic Drug Officer Monthly.
- 5.4 Procedure of Administration and discarding of unused Narcotic & Controlled drugs**
- 5.4.1 Administration of Narcotic drugs & controlled drug done by Registered Nursing Officers/staff under supervision of a Registered RMP.
- 5.4.2 The remaining unused drug of ampoules discarded in the sink by Nursing Officers/staff under supervision of a RMP.
- 5.4.3 Administration and discard records should be filled in Narcotic consumption book.
- 5.4.4 No cutting and overwriting allowed in Narcotic consumption book, if an error occurs it should be cross by a single line and mark "ERROR" then signed by two Nursing Officers or RMP.
- 5.4.5 Patches after removing discarded by nurses, the used patch is folded in half so that the sticky side sticks to itself and is flushed down the toilet.
- 5.5.8 Empty ampoules have to be discarded as per BWM protocol and details of the same be mentioned in the Narcotic Log Book (with one officer signature and ANS of respective ward) maintained at user department level.
- 5.5 Procedure for returning Narcotic Drugs**
- 5.5.1 Rejected Narcotic & controlled substances resulting established ADR/ADE may be returned to Central Pharmacy if they are still in the original unopened tamper proof packaging.
- 5.5.2 The unused tablet from strip of tablet must be cutted as to remain B. No. and expiry date on remaining portion of strip and same may be recirculated interdepartmentally under supervision of ANS with proper documentation in NLB .
- 5.5.3 Narcotic drug & Controlled drugs returned to the Central Pharmacy are delivered by a Registered nursing officer, pharmacist.
- 5.5.4 Two licensed staff (Registered pharmacist/ Registered Nursing Officer/ RMP) must witness the return.

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5.5.5 If the package has been opened or the tamper seal removed, it must be discarded by discarding procedures.

5.6 Discrepancy Resolution

5.6.1 Any discrepancy in the count of controlled substances or disposition of the narcotic keys is resolved by the end of the shift during which it is discovered.

5.6.2 Resolution can be achieved by review of dispensing and returns records and consulting with all staff with access.

5.6.3 If case of Narcotic key loss inform Faculty in-charge Pharmacy/ Essential Narcotic Drug Officer, ANS of respective department and security, If key found within one hour check the whole stock of Narcotic & controlled drugs in front of security and Central Pharmacy in-charge (for Central Pharmacy) and Assistant Nursing Superintendent (for respective ward/department).

5.6.3.1 If stock found improper the person who missed the key is responsible for it. The management will decide what action should be done in this case.

5.6.3.2 If key not found within one hour, call the Engineering person and change the lock and check the stock if stock found improper refer 5.6.3.1 rules.

5.6.4 Any discrepancies which cannot be resolved must be reported immediately as follows:

5.6.4.1 Complete Occurrence Report to Risk Management, detailing the discrepancy, steps taken to resolve it, and the names of all registered staff working when the discrepancy was noted;

5.6.4.2 The unit manager or designee must also report any loss of controlled substances where theft is suspected to security.

5.5 Staff may not leave the area until discrepancies are resolved or reported as unresolved discrepancies.

5.6 Procedure of discarding empty ampoules

5.6.1 The Committee nominated by competent authority AIIMS Raipur may check Central Pharmacy and respective wards periodically and permit to discard the empty ampoules then after the empty ampoules may be send as per BWM protocol/ for incineration to the government authorized body.

5.7 Warning and Cautions:

It is being requested by the Residents (Junior Residents/Senior Residents) to maintain the Ampoules/Vials/other NDPS drugs with at most care. The empty/Accidental broken materials should be duly handover to the technical person (OT in-charge /Pharmacist/Nursing Officer) in charge to preserve deficiency of information in the log book. The consultant in-charge of respective departments should be vigilant as for above matter.

5.7.1 **Missed Broken Information Report (MBIR Form):** MBIR form (Part B of annexure) to be filled mandatory in case of any missing of ampoule is discovered.

5.8 Sub store Custodian:

The departments/sub custodian may be nominated by competent authority AIIM Raipur for keeping stocks of NDPS drugs as per need and as per extent rules.

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Part A

Narcotic Consumption Book

| S.No. | Name of product | Dosage form | Department | Patient name | Prescriber | Unit | Qty. Received | Qty. Used | Qty. Discarded | Remarks | Signature 1 | Signature 2 |
|-------|-----------------|-------------|------------|--------------|------------|------|---------------|-----------|----------------|---------|-------------|-------------|
| | | | | | | | | | | | | |

Narcotic Log Book

| S.No. | Name of product | Dosage form | Department | Unit | Qty. Received | Qty. in Hand | Qty. issued | Remarks | Signature 1 | Signature 2 |
|-------|-----------------|-------------|------------|------|---------------|--------------|-------------|---------|-------------|-------------|
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Part B

MBIR FORM

Date:

Name of the Drug:

Quantities:

Department:

Reason:

Signature of In-charge/Faculty of Department:

Signature of ENNO:

Signature of Pharmacist (opioids dealing):

Signature of END Officer

*MBIR -MissedBroken Information Report

* END - Essential Narcotic Drugs

* ENNO - Essential Narcotic Nursing Officer

*MIBR to be reported within 24hrs.

*Faculty in-charge of respective department may provide awareness for JR/SR regarding the importance of empty vials for future audits and accounting.

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